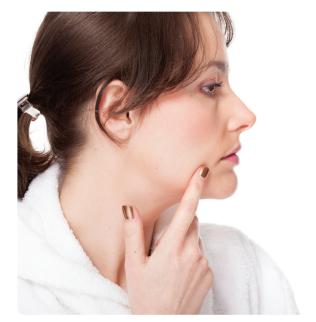
Topical Acne Products Can Cause Dangerous Side Effects

ertain acne treatments can, in rare instances, cause severe allergic reactions that are potentially life-threatening.

The Food and Drug Administration (FDA) is warning that the use of certain acne products containing the active ingredients benzoyl peroxide or salicylic acid can cause rare but serious and potentially life-threatening allergic reactions or severe irritation. An active ingredient is the component that makes the medicine effective against the illness or condition it is treating.

The acne products the FDA is warning about are sold over-the-counter (OTC) and applied to the skin (topical). Their serious allergic reactions differ from the less harmful irritations already included in the product Drug Facts labels, which include burning, dryness, itching, peeling, redness, and slight swelling where the product is applied.

"There is currently no mention of the possibility of these very severe





allergic reactions on the product labels," says Mona Khurana, M.D., a medical officer at FDA. "It's important that consumers know about them, and that they know what to do if they occur."

Consumers can find out if an OTC topical acne product contains benzoyl peroxide or salicylic acid by looking at the Active Ingredient(s)

section of the Drug Facts label on the product package.

FDA has issued a Drug Safety Communication (DSC) to inform both consumers and health care professionals of the potential dangers of these products.

Products of concern are marketed under different brand names such as Proactiv, Neutrogena, MaxClarity, "There is currently no mention of the possibility of these very severe allergic reactions on the product labels...It's important that consumers know about them, and that they know what to do if they occur."

Oxy, Ambi, Aveeno, and Clean & Clear. They are available as gels, lotions, face washes, solutions, cleansing pads, toners and face scrubs.

From 1969 through January 28, 2013, FDA received 131 reports from both consumers and manufacturers of allergic and hypersensitivity-related adverse reactions associated with these products. About 42% of these reactions occurred within minutes to 24 hours of use. The affected persons ranged in age from 11 to 78 years.

Types of Reactions

Forty percent of these reports described severe allergy symptoms such as throat tightness, shortness of breath, wheezing, low blood pressure, fainting or collapse. Isolated instances of hives, itching of face or body (even of parts of the body where the person did not apply the medication), and swelling of eyes, face and lips were also reported.

Based on the information reported, FDA cannot determine if these reactions were triggered by the products' active ingredients, the inactive ingredients, or a combination of both.

While no deaths have been reported, 44% of the cases required hospitalization.

"FDA will continue to monitor closely and evaluate this safety issue," Khurana says. The agency is also encouraging manufacturers to use the drug label to advise consumers how to test the product's safety before using it for the first time.

For example, Khurana suggests that new users should apply a small amount of the product to a small affected area for three days. If no discomfort occurs, they can follow the labeled directions for normal use.

What to Do If a Bad Reaction Occurs She adds that there are a number of important safety actions to counter an allergic reaction, including:

 Avoid using the product if you've had previous allergic or hypersensitivity reactions.

- Stop using the product if you develop hives or itching of the face or body.
- Stop using the product and seek immediate medical attention if you develop throat tightness or swelling of the eyes, face, lips or tongue; feel faint; or have difficulty breathing.

FDA encourages consumers to report any negative reactions or side effects from use of these products to the FDA's MedWatch program.

Find this and other Consumer Updates at www.fda.gov/ForConsumers/ConsumerUpdates

Sign up for free e-mail subscriptions at www.fda.gov/consumer/consumerenews.html